

**VOLUNTARY COUNSELING AND
TESTING FOR HIV
A STRATEGIC FRAMEWORK**



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I. INTRODUCTION

The HIV epidemic continues to spread at an alarming rate with over 6,000 new infections per day. While the epidemic is now spreading rapidly in some parts of Asia and Latin America and Caribbean, Sub-Saharan Africa continues to bear the greatest burden of disease. HIV prevalence exceeds 30 percent among sexually active adults in some African cities, and AIDS is the leading cause of death in major cities within Sub-Saharan Africa.

More than 90 percent of the 34 million people living with HIV/AIDS around the world live in resource-constrained countries in Africa, Asia, Latin America and Caribbean. However, despite the very high number of people already living with HIV/AIDS, it is estimated that less than 10 percent of them are aware of their HIV serostatus mainly because of the limited availability, access, and use of HIV counseling and testing services (VCT).

HIV voluntary counseling and testing has long been a component of HIV prevention and care efforts in developed countries, but only recently is it increasingly being implemented in resource-constrained countries. In the presence of a high prevalence of HIV, and the growing awareness several governments have included voluntary HIV counseling and testing services as a major component of their national HIV prevention and care programs.

Despite the recognized importance of VCT in national AIDS control programs, VCT services are not fully developed in most resource-constrained countries. Where available, these services tend to be of limited quality and coverage, they are implemented by NGOs and some public and private clinics and hospitals. These services are limited because of lack of trained staff, concerns about confidentiality, stigma and discrimination, lack of knowledge about the existence and benefits of the VCT services by potential clients, and the lack of financial resources to cover the cost of running such services (e.g. test kits, staff salaries, etc.). There is clearly a need to strengthen and expand VCT services. This document describes FHI's strategy and contribution to the efforts to improve VCT services.

II. STATE-OF-THE-ART: VCT AS A MAJOR COMPONENT OF COMPREHENSIVE HIV/AIDS CONTROL PROGRAMS

Several observational studies were first to suggest the feasibility and effectiveness of VCT. For example, in 1991 a study conducted among 149 discordant couples (one HIV-infected and the other HIV-negative) in Kinshasa, Congo, demonstrated a marked increase in condom among these couples, from less than 5 percent before the VCT intervention to 70 percent following the intervention [Kamenga *et al.*, 1991]. Another study carried out in Rwanda on the impact of VCT among a cohort of women reported an increase in condom use from only 7 percent having ever used condom before the intervention to 16 percent among HIV-seronegative and 35 percent among HIV-seropositive women [Allen *et al.*, 1992]. Finally, an analysis of data from 3000 clients receiving VCT at the AIDS Information Center in Uganda, demonstrated substantial reduction in risk behaviors at 3 and 6 months following the intervention [Campbell *et al.*].

Findings from observational studies have been confirmed by a study conducted by FHI in collaboration with UNAIDS and WHO. This multi-center (including Kenya, Tanzania, Trinidad and Tobago) randomized controlled study coordinated by the Center for AIDS Prevention Studies documented a 43 percent reduction in the occurrence of unprotected sex among those who received VCT [the voluntary HIV-1 Counseling and Testing Study Group]. In addition to the behavioral data, this

study also demonstrated that VCT is highly cost-effective. Although slightly less cost-effective than interventions such as improvement of sexually transmitted disease services and universal provision of Nevirapine to pregnant women in high-prevalence settings, VCT compares well with other interventions and its cost-effectiveness can be significantly improved with targeting [*Sweat et al.*].

Based on the existing data and evidence, there is currently a consensus about the efficacy and cost-effectiveness of the VCT intervention for HIV prevention and care. VCT has become or is being advocated as a major component of any comprehensive national AIDS control program in many countries. Major roles recognized for VCT include:

- Enabling VCT clients to cope and take personal decisions related to HIV/AIDS
- Assisting VCT clients to initiate and maintain preventive behaviors
- Serving as an entry point to other HIV prevention and care and support services
- Helping to combat stigma and discrimination in the community.

III. FHI GOALS AND OBJECTIVES

FHI's goal on VCT is to contribute to the reduction of HIV transmission through behavior change especially among populations most at risk for HIV infection and contribute to meeting the unmet care and support needs of people living with HIV/AIDS, their families and communities. Specific objectives of our VCT efforts are to:

- 1) Improve the local capacity to provide VCT,
- 2) Improve/promote availability and use of VCT services,
- 3) Promote linkages between VCT services and other care and support services (AIDS care and the care continuum of services),
- 4) Promote strategies aimed at reducing stigma and discrimination

IV. FHI's TECHNICAL AND PROGRAMMATIC APPROACHES

Guiding principles

FHI recognizes that counseling is a culturally sensitive and complex intervention. We therefore support working with in-country counterparts and the community including PLHAs to develop culturally appropriate VCT services based on the client-centered approach to counseling.

Beyond the counseling sessions and testing (if desired by the client) of specimens, VCT is an important entry point to many other care and support services. Therefore, the expansion and promotion of HIV VTC services must be done with special care to ensure that the needs of those using the promoted services will be met to the extent possible. For example, massive promotion of VCT not coordinated with the development and/or strengthening of other care and support services and referral networks may result in poor quality services and fall short of meeting the needs of PLHAs. For VCT to fully play its role in HIV/AIDS prevention and care, it must be of the best quality, available, and easily accessible to those who need such service. The existence of effective referral systems between VCT

and other care and support services in the community is critical in responding to the needs of people infected or affected by HIV/AIDS.

Quality assurance of both HIV testing and counseling is critical to the success of VCT services. FHI contributes to quality assurance through the development of standard operating procedures, training, supervision and support of staff, and the establishment of both internal and external quality control systems.

FHI's approaches

FHI tailors the design and implementation of VCT services to the unique epidemiological, behavioral, and economic context of each country and setting in order to maximize its effectiveness and cost-effectiveness.

We also pay particular attention to the choice of VCT service delivery models in each country and setting. Both self-standing and integrated VCT services have advantages and disadvantages. Selecting one approach over the other or going for a mix of both self-standing and integrated models must be done carefully taking in consideration factors such as: the choice of the local authorities, the target populations, level of stigma and discrimination in the community, management and administration ease, potential for linkages, existing demand and likelihood of service utilization, equity issues, feasibility, ability to be replicated, etc. Whatever the model of service delivery, every effort must be made to ensure that the counseling provided remains of the highest quality possible. For example, while group pre-test information sessions can be employed at VCT service sites with heavy client flow to reduce the length of the individual/pre-test counseling and reduce burden on the counselors, these should not be seen as a replacement to pre-test counseling.

The choice of the HIV testing protocol must consider the local HIV epidemiology, the locally existing laboratory infrastructure, the volume of HIV testing (i.e. number of people to be tested daily), the quality assurance capacity, the clients' preference, the impact of the chosen protocol on the provision of the service, and the long-term cost implication of the chosen protocol. Various protocols and strategies can be considered and it is normally the responsibility of government regulatory bodies (MOH or NACP) to formulate the most feasible testing strategies for the country. FHI supports the current World Health Organization recommendations on HIV testing strategies based on the objectives for testing and prevalence of HIV infection in the sample population. The main objectives for HIV testing are blood transfusion safety, surveillance, and diagnosis. The textbox below summarizes the strategy recommended for diagnosis also applicable to VCT.

Prevalence	Strategy
Symptomatic > 30%	I
Symptomatic ≤ 30%	II
Asymptomatic > 10%	II
Asymptomatic ≤ 10%	III

Strategy I

All samples are tested using one ELISA or rapid/simple test. Samples that are reactive are considered HIV antibody positive and those that are non-reactive are considered antibody negative.

Strategy II

All samples are first tested using one ELISA or rapid/simple test. Any reactive samples are subjected to a second test based on a different test principle and/or a different antigen preparation. Samples that are reactive by both tests are considered HIV antibody positive. Samples that are non-reactive by the first are considered non-reactive and those that are reactive by the first test but non-reactive by the second test are also considered antibody negative.

Strategy III

All samples are first tested using one test. Any reactive samples are re-tested using a second test. Samples found reactive by the second test are subjected to a third and different test. Samples reactive by all three tests is considered HIV antibody positive and samples that are non-reactive by the first test are considered as negative as serum that initially reactive but non-reactive with the second test. Samples that are initially reactive by the first and second tests but non-reactive with the third test are considered to be equivocal.

(WHO Weekly Epidemiological Record #12, Mar 1997)

It is important to make special efforts to avail VCT services to particular groups (youth, couples, pre-marital couples, other high risk and vulnerable groups) that may greatly benefit from such service. Of particular interest are adolescents. Given the declining age of onset of first sexual activity, providing youth friendly VCT services must be considered as a pivotal investment in the future of many nations, especially within sub-Saharan Africa FHI's programmatic approach to implementing VCT services is as follows: 1) support the conduct of baseline analysis including the identification and meeting with stakeholders, gathering of background information on existing VCT services, inventory of care and support services, and exploration of needs and expectations of potential VCT clients; 2) support project design using information gathered in point one above; 3) support the implementation of VCT services, and 4) provide appropriate assistance with quality assurance and monitoring and evaluation. FHI supports countries in the following specific areas:

Policy

- Advocacy for VCT services to policymakers, and leaders at various levels
- Development of national guidelines on HIV counseling and testing
- Development of standardized HIV counseling training curricula
- Development of appropriate VCT training materials
- Involvement of the community to promote acceptability of VCT services, acceptance of those living with HIV/AIDS, and reduction of stigma and discrimination.

Service promotion

- Use of appropriate media to advertise and promote VCT services to increase demand for VCT.

VCT services

- Assess the availability, quality and use of existing VCT services if any
- Design, implementation and scaling up of high quality VCT services
- Training of counselors in risk-reduction counseling as well as in personal emotional support techniques
- Training of laboratory personnel
- Providing support for quality assurance (e.g. quality control for HIV testing; supervision and quality control for HIV counseling)
- Development of directory of care and support services to facilitate referrals
- Establish/promote linkages between VCT services and other care and support services as appropriate

Research and evaluation

- Provide ongoing technical assistance to improve the implementation, monitoring and evaluation of VCT services
- Support the development of a limited number of VCT sites as learning centers and use experience gained from doing to expand VCT services in the country.
- Support collection and dissemination of lessons learned

V. ILLUSTRATIVE ACTIVITIES

Following are some illustrative FHI's undertakings related to VCT:

West Africa (Ivory Coast, Cameroon, Togo, Burkina Faso): Baseline assessment of VCT in each country and development of counselors' training manual, training of counselors, organizational and technical capacity building of local organizations in providing VCT, support and reinforcement of referral systems and resources, and assistance in development of national guidelines.

Kenya: In support to the VCT efforts by the government of Kenya, FHI is in the process of establishing a number of VCT centers throughout the country (projected at 28 VCT sites to attend to 28,200 new clients by the end of 2001), focusing in the IMPACT geographic priority areas in order to promote linkages and referrals with the other ongoing HIV prevention and care and support activities. The VCT sites are expected to primarily target youth aged 18-24 years and sexually active adults males and females and will offer same day counseling and testing service. FHI envisions the formation of post-test clubs as part of the VCT activities and will promote the VCT services as part of the continuum of the prevention and care strategy using both mass media and interpersonal communication. In collaboration with the NASCOP and other partners, FHI also contributed to the development of national guidelines on counseling, training and testing and will support the training of appropriate staff for the provision of VCT.

Zimbabwe: As a sub-contractor to the AIDSMARK VCT activities in Zimbabwe, FHI contributed to the baseline assessment of VCT services (availability, counseling quality, laboratory services, testing algorithms and policies), development of a counseling training manual, technical assistance to the NACP and AIDSMARK in the establishment of VCT services, quality assurance, and monitoring and evaluation of the VCT services.

Rwanda: In collaboration with Rwanda's NACP, FHI is the lead organization in Rwanda supporting decentralization of VCT services, primarily to hospitals and health centers around the country. FHI/IMPACT's support has included training in counseling and rapid testing, site renovation, provision of equipment, medical supplies and furniture and the introduction of a computerized record-keeping system. In 2000, FHI/IMPACT supported the establishment of three VCT sites outside of Kigali in Kabgayi, Ruli and Rwamagana District Hospitals. The services at these sites are unique in Rwanda in that they each offer full-time counseling and provide anonymous and rapid testing. Prior to IMPACT support, VCT data was kept by client name, and blood samples for HIV testing were sent to the National Laboratory of Retrovirus Infections, resulting in a two week to three-month delay in receiving results and a loss to follow-up of many clients. Since FHI/IMPACT began supporting the

regional sites, number of people benefiting from VCT has increased by 25 percent. More importantly, the percentage of clients who actually receive their results has increased dramatically from a low of 58 percent at one site to 89 to 96 percent currently reported at the three sites. In 2001, FHI/IMPACT will support the development of at least 17 more VCT sites.

VI. INTERVENTION-LINKED RESEARCH

There are still many unanswered operational questions related to the implementation of VCT in resource-constrained countries. FHI strives to conduct well-designed intervention-linked research as part of our VCT supported activities with the goal to improve VCT service design and implementation.

Illustrative intervention-linked research questions include:

- What is the impact of support groups on the long-term sustainability of behavior change achieved through voluntary VCT?
- What is the community impact of voluntary VCT?
- How can VCT be integrated efficiently and affordably (inexpensively) in STD, family planning services, and MTCT services?
- Are there models of VCT delivery that are more cost-effective than others?
- What is the added value of parallel HIV testing on serial testing as recommended by WHO?

VII. MONITORING AND EVALUATION

Monitoring and evaluation (M&E) is a critical component for the successful implementation of VCT services. Well designed and conducted M&E of VCT will help identify and correct potential problems on an ongoing basis and provide feedback in the process of planning, designing, and implementing of VCT programs.

Monitoring and evaluation activities should address two areas of relevance for service providers and policy makers, which are:

- Service delivery – how well voluntary counseling and testing is provided; and
- Program effectiveness – the intermediate outcomes and long-term impact that HIV voluntary counseling and testing may have on the population receiving the service.

Illustrative indicators include:

Process indicators: service delivery or program output

- Proportion of people in the community who know about the VCT services
- Number of people counseled and tested at the VCT site (per month, per year)
- Proportion of people counseled and tested who have returned to receive their test results
- Proportion of people testing HIV positive who have been referred to appropriate care and support services
- Proportion of people counseled and tested who state that they intend to inform their partners.

- Proportion of people counseled and tested who have informed their partners (partner notification)

Effectiveness indicators: intermediate program outcomes

- Changes in HIV/STI-related risk behaviors among VCT clients and their partners
- Changes in behavior among people stating that they know their serostatus (collected through BSS, for example).
- Changes in STI trends in sub-populations reached by the VCT program
- Reduced stigmatization of, and discrimination against, people in the community affected by HIV/AIDS
- Increased community support for people living with HIV/AIDS

Effectiveness indicators: expected program impact (long-term effects)

- Changes in trends in HIV incidence/prevalence in the population or sub-populations served by VCT programs
- Reduced mother-to-child transmission of HIV infection in women of childbearing age targeted by the VCT programs
- Sustained changes in societal norms in the community reached by the VCT programs

VIII. LINKAGES AND PARTNERSHIPS

FHI recognizes the importance of linkages between VCT and our other prevention and care activities. VCT is an important component of our prevention activities for risk reduction and is used as an entry point for our care activities such as TB prophylaxis and treatment, medical care, prevention of mother-to-child transmission, establishment of support networks, etc. For example, in Kenya VCT is used as an entry point to treatment and prophylaxis activities for tuberculosis. Our VCT expertise is also used to support ongoing activities to prevent mother-to-child transmission of HIV in Kenya and Rwanda.

In addition FHI strives to collaborate with NGOs, and community based organizations, and other national and international organizations involved in VCT activities. It is in this context that we collaborated with the World Health Organization, the United Nations Joint Program on AIDS, the Center for AIDS Prevention Studies, the Kenya Association of Professional Counselors, the Muhimbili University College of Health Sciences (Tanzania), and the Queens Park Counseling Center (Trinidad) in the conduct of a multi-center randomized study of the efficacy of VCT. We are currently working with PSI/AIDSMARK in Zimbabwe and collaborating with the Centers for Disease Control and Prevention in Kenya and Côte d'Ivoire.

IX. FURTHER READING

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APPENDIX I: Parallel vs. Serial HIV Rapid Testing Protocol

Definitions:

Parallel testing: Two different tests are used for each client. If the two initial test results are concordant (either HIV-positive or HIV-negative), the result is reported to the client. If the initial results are discordant, a third test is used as a tiebreaker.

Serial testing: One screening test is first used on each client, followed by a different test for all samples that initially tested HIV-positive. In case of discordance of results between the first and the second tests, a third test is used as a tiebreaker.

Pros and cons of each approach

	Pros	Cons
Parallel testing	<ul style="list-style-type: none"> Shorter waiting time may lessen time taken from work, resulting in a lower cost to the client and less anxiety while waiting for results. Having only one finger stick reduces the potential for stigma Clients perception that two tests are better than one, reducing shopping around, and wining public trust Blood samples taken by finger prick are suited for conditions in the field (e.g. mobile clinics, remote areas, doctor's offices etc.) <p><i>Note: the last three may be applicable to serial testing depending on how the service is organized</i></p>	<ul style="list-style-type: none"> Several published studies report that there is no significant increase in accuracy with parallel testing rather than serial testing: <ol style="list-style-type: none"> Wilkinson et al. <i>AIDS</i> 1997,11:337-381 Anderson et al. <i>AIDS</i> 1997; 11; 1815-1822 More expensive than serial testing (can be more than 50 percent more expensive depending on the HIV prevalence as shown in illustration below) Using finger prick makes it difficult to organize quality control. May require to additional blood collection from selected clients for quality control.

	Pros	Cons
Serial Testing	<ul style="list-style-type: none"> Currently recommended protocol by both WHO (<i>Weekly Epidemiological Record</i> #12, Mar 1997) and CDC (Mar 27, 1998 <i>Morbidity and Mortality Weekly Report</i>) Several published studies have demonstrated that serial testing using rapid tests yield highly accurate test results (predictive values). The results are equivalent, and in some cases better than the standard algorithm of EIA followed by Western blot. Drawing of a venipuncture sample makes it possible to have extra samples that can be archived for quality assurance purposes as well as avoiding the necessity for recalling patient for a second test. Less cost, increasing chances for sustainability, freeing up funding for other interventions or for wider reach of VCT. 	<ul style="list-style-type: none"> Possibility of longer waiting time for clients that test positive on first test. <i>However</i>, this can be minimized through an appropriate clients' flow. Additionally, this time can be used to provide health information and to minimize anxiety; video or other distractions may be provided. Potential for stigmatizing clients who test positive. <i>However</i>, this can be handled by organizing patient flow so that all patients are handled in a similar fashion (same waiting time, one veni-puncture) Might require EDTA test tube, which will add to cost. <i>However</i>, the cost of US 7 cents per one EDTA tube is less than adding another test. <p><i>Previous recommendations were based on serum- and plasma - based tests, not whole blood tests. But this protocol can easily be evaluated in any country</i></p>

Illustrative comparison of the two approaches

The cost of HIV testing will vary significantly depending on the HIV prevalence of the target population and the percent agreement of the tests used as illustrated in the 3 scenarios below:

Scenario I

Assumptions: Population of 28,000 with 30 percent HIV prevalence

Scenario Ia: Percent agreement of 99 percent for parallel and serial testing

	Cost per test in US dollars	Parallel testing (1% discordance)		Serial testing (1% discordance)		Percent cost difference
		Number of tests	Total cost	Number of tests	Total cost	
Test A	1.5	28,000	42,000	28,000	42,000	
Test B	2.2	28,000	61,600	8,400	18,480	
Test C	2.2	280	616	84	185	
Total Cost			104,216		60,665	41.8%

Scenario Ib: Percent agreement of 99 percent for parallel and 90 percent for serial testing

	Cost per test in US dollars	Parallel testing (1% discordance)		Serial testing (10% discordance)		Percent cost difference
		Number of tests	Total cost	Number of tests	Total cost	
Test A	1.5	28,000	42,000	28,000	42,000	
Test B	2.2	28,000	61,600	8,400	18,480	
Test C	2.2	280	616	840	1,848	
Total Cost			104,216		62,665	39.9%

Scenario II

Assumptions: Population of 28,000 with 20 percent HIV prevalence

Scenario IIa: Percent agreement of 99 percent for parallel and serial testing

	Cost per test in US dollars	Parallel Testing (1% discordance)		Serial Testing (1% discordance)		Percent cost difference
		Number of tests	Total cost	Number of tests	Total cost	
Test A	1.5	28,000	42,000	28,000	42,000	
Test B	2.2	28,000	61,600	5,600	12,320	
Test C	2.2	280	616	56	124	
Total Cost			104,216		54,444	47.8%

Scenario IIb: Percent agreement of 99 percent for parallel and 90 percent for serial testing

	Cost per test in US dollars	Parallel testing (1% discordance)		Serial testing (10% discordance)		Percent cost difference
		Number of tests	Total cost	Number of tests	Total cost	
Test A	1.5	28,000	42,000	28,000	42,000	
Test B	2.2	28,000	61,600	5,600	12,320	
Test C	2.2	280	616	560	1,232	
Total Cost			104,216		55,552	46.7%

Scenario III

Assumptions: Population of 28,000 with 10 percent HIV prevalence

Scenario IIIa: Percent agreement of 99 percent for parallel and serial testing

	Cost per test in US dollars	Parallel testing (1% discordance)		Serial testing (1% discordance)		Percent cost difference
		Number of tests	Total cost	Number of tests	Total cost	
Test A	1.5	28,000	42,000	28,000	42,000	
Test B	2.2	28,000	61,600	2,800	6,160	
Test C	2.2	280	616	28	62	
Total Cost			104,216		48,222	53.7%

Scenario IIIb: Percent agreement of 99 percent for parallel and 90 percent for serial testing

	Cost per test in US dollars	Parallel testing (1% discordance)		Serial testing (10% discordance)		Percent cost difference
		Number of tests	Total Cost	Number of tests	Total cost	
Test A	1.5	28,000	42,000	28,000	42,000	
Test B	2.2	28,000	61,600	2,800	6,160	
Test C	2.2	280	616	280	616	
Total Cost			104,216		48,776	52.7%

Note: Based on the above scenarios, the cost per HIV-infection identified varies from **\$7.2-\$17.4** when using serial testing as compared to **\$12.4-\$37.2** when using parallel testing.



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